Remarks:

Claims 1-9, 12, 13 and 16-25 are pending.

Claim 1 is amended to recite a sustained release oral formulation comprising biodegradable microparticles and/or nanoparticles having therapeutic agents dispersed therein. Support for this amendment can be found in the specification, for example on page 33, line 10 to page 34, line 17.

No new matter is introduced by way of this amendment and entry thereof is respectfully requested.

I. Information Disclosure Statement

Applicants thank the Examiner for considering the IDS filed on October 17, 2006. As requested by the Examiner, page 1 of the IDS has been corrected to list the application number (10/687,706) and is being submitted concurrently herewith along with the appropriate USPTO Form 1449.

II. Rejections under 35 U.S.C. §102(b)

Claims 1-4, 6-9 and 16-18 are rejected under 35 U.S.C. §102(b) as being anticipated by Cohn (US Patent 4,868,179). Applicants respectfully traverse this rejection.

The claims as amended are directed to sustained release oral formulations comprising biodegradable microparticles and/or nanoparticles having dispersed therein a therapeutically effective amount of at least one antioxidant and at least one of isosorbide dinitrate and isosorbide mononitrate, wherein the isosorbide dinitrate is present in an amount of about 30 milligrams per day to about 160 milligrams per day.

Cohn is cited by the Examiner for teaching a composition comprising hydralazine hydrochloride and isosorbide dinitrate within the dosage range of claim 1. However, Cohn's composition is not a sustained release formulation comprising biodegradable microparticles and/or nanoparticles having at least one antioxidant and at least one of isosorbide dinitrate and isosorbide mononitrate dispersed therein.

Applicants submit that Cohn does not anticipate the claims as amended and withdrawal of this rejection is respectfully requested.

III. Rejection under 35 U.S.C. §103

Claims 1-4, 6-9, 12-13 and 16-25 are rejected under 35 U.S.C. §103 as being unpatentable over Cohn (U. S. Patent No. 4,868,179) in view of Klemsdal (Eur. J. Clin. Pharmacol. 1994), Wikipedia, and Chobanian et al (U. S. Patent No. 5,645,839).

Applicants respectfully traverse the rejection and respectfully submit that the claimed invention is unobvious over the cited references and there is no motivation to combine the cited references to arrive at the presently claimed invention. Applicants respectfully submit that the cited references, individually or in combination, do not disclose or suggest, or provide motivation to arrive at the presently claimed invention.

The claims as amended are directed to sustained release oral formulations comprising biodegradable microparticles and/or nanoparticles having dispersed therein a therapeutically effective amount of at least one antioxidant and at least one of isosorbide dinitrate and isosorbide mononitrate, wherein the isosorbide dinitrate is present in an amount of about 30 milligrams per day to about 160 milligrams per day.

As noted previously, Cohn's composition is not a sustained release formulation comprising biodegradable microparticles and/or nanoparticles having at least one antioxidant and at least one of isosorbide dinitrate and isosorbide mononitrate dispersed therein. The specification defines "sustained release" on page 5, line 31 to page 6, line 3 as the release of a therapeutically active compound such that blood levels of the therapeutically active compound are within a desirable therapeutic range over an extended period of time. As further described in the specification on page 33, line 10 to page 34, line 17, sustained release formulations of the invention can be achieved by encapsulating the therapeutic agents in biodegradable dosage forms such as microparticles, nanoparticles, and the like, wherein the therapeutic agents are dispersed within the dosage form. Biodegradation of the dosage form over time releases the therapeutic agents for cellular uptake.

Applicants submit that nowhere in the teachings of Cohn is there any suggestion or motivation to make sustained release formulations comprising biodegradable microparticles and/or nanoparticles having dispersed therein a therapeutically effective amount of at least one antioxidant and at least one of isosorbide dinitrate and isosorbide mononitrate.

Klemsdal and the Wikipedia entry are cited by the Examiner for teaching the similar effect of administering either isosorbide dinitrate or isosorbide mononitrate. However, neither Klemsdal nor Wikipedia cures the deficiencies of Cohn, as neither reference teaches or suggests sustained release formulations comprising biodegradable microparticles and/or nanoparticles having at least one antioxidant and at least one of isosorbide dinitrate and isosorbide mononitrate dispersed therein.

Chobanian is cited by the Examiner for teaching a composition comprising an ACE inhibitor, a nitric oxide stimulator and at least one pharmaceutically acceptable carrier. However, Chobanian does not cure the deficiencies of Cohn, as Chobanian does not teach or suggest sustained release formulations comprising biodegradable microparticles and/or nanoparticles having at least one antioxidant and at least one of isosorbide dinitrate and isosorbide mononitrate dispersed therein

In view of the above, Applicants submit that the claims are patentable over the combination of Cohn, Klemsdal, Wikipedia, and Chobanian. Withdrawal of this rejection is respectfully requested.

IV. Conclusion

In view of the above amendment, Applicants believe the pending application is in condition for allowance.

No fees are believed to be due with this response. However, the Commissioner is authorized to charge necessary fees, or credit any overpayments, to our Deposit Account No. 08-0219, under Order No. 0102258.00170US2 from which the undersigned is authorized to draw.

Respectfully submitted,

Dated: January 16, 2008

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